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\*Practice limited to Federal Agencies

March 17, 2004

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1636**

Re: U.S. Utility Patent Application  
Application No. 10/685,802; Filed: October 16, 2003  
For: **Dry Powder Cells and Cell Culture Reagents and Methods of  
Production Thereof**  
Inventors: FIKE *et al.*  
Our Ref: 0942.4290008/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Listing of the cited documents on Form PTO-1449 (13 sheets); and
3. One (1) return postcard.

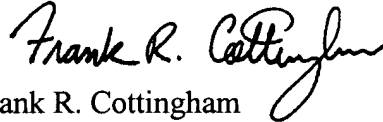
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
March 17, 2004  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, reading "Frank R. Cottingham". The signature is written in a cursive, flowing style.

Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

FRC/shr  
Enclosures

SKGF\_241152.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Fike *et al.*

Appl. No. 10/685,802

Filed: October 16, 2003

For: **Dry Powder Cells and Cell  
Culture Reagents and Methods  
of Production Thereof**

Confirmation No. 5140

Art Unit: 1636

Examiner: *To be assigned*

Atty. Docket: 0942.4290008/RWE/FRC

### Information Disclosure Statement

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of all documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/606,314, Fike *et al.*, filed June 29, 2000, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents **AM1, AO1, AL2, AM2, AN2, AO2, AP2, AM3** and **AN3** cited on Form PTO 1449:

Document **AM1**, Czechoslovakian Patent Publication No. CS 169,007, is in the Czechoslovakian language. An English language abstract of document **AM1** is attached as document **AS4**.

Document **AO1**, Japanese Patent Publication No. JP 51-98354, is in the Japanese language. An English language abstract of document **AO1** is attached as document **AS8**.

Document **AL2**, Japanese Patent Publication No. JP 57 152882, is in the Japanese language. An English language abstract of document **AL2** is attached as document **AT8**.

Document **AM2**, Soviet Union Patent Publication No. SU 1097253, is in the Russian language. An English language abstract of document **AM2** is attached as document **AR9**.

Document **AN2**, European Patent Publication No. EP 0 155 427 A1, is in the French language. An English language abstract of document **AN2** is attached as document **AS9**.

Document **AO2**, Japanese Patent Publication No. JP 1 157395, is in the Japanese language. An English language abstract of document **AO2** is attached as document **AT9**.

Document **AP2**, Japanese Patent Publication No. JP 2-57175, is in the Japanese language. An unverified English language translation of document **AP2** is attached as document **AR10**.

Document **AM3**, Japanese Patent Publication No. JP 4 198137, is in the Japanese language. An English language abstract of document **AM3** is attached as document **AS10**.

Document **AN3**, Danish Patent Publication No. DK 167090, is in the Danish language. An English language abstract of document **AN3** is attached as document **AT10**.

The Examiner's attention is directed to the following co-pending U.S. Patent Application, which is directed to related technical subject matter: U.S. Patent Application

No. 09/705,940, Fike *et al.*, filed November 6, 2000 and submitted herewith as document **AS12**.

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

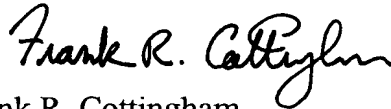
Fike *et al.*  
Appl. No. 10/685,802

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

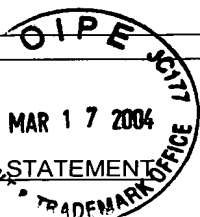
The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,  
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

Date: MAR. 17, 2004  
1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
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FORM PTO-1449 MAR 17 2004

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0942.4290008/RWE/FRCAPPLICATION NO.  
10/685,802FIRST NAMED INVENTOR  
Fike *et al.*FILING DATE  
October 16, 2003ART UNIT  
1636

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	3,771,237	11/13/1973	Hansen <i>et al.</i>			04/04/1972
	AB1	4,071,412	01/31/1978	Eisenberg <i>et al.</i>			05/05/1975
	AC1	4,072,570	02/07/1978	Williams			02/20/1976
	AD1	4,073,951	02/14/1978	Sargeant			08/25/1976
	AE1	4,490,403	12/25/1984	Pisecky <i>et al.</i>			06/13/1983
	AF1	4,511,592	04/16/1985	Percel <i>et al.</i>			06/20/1984
	AG1	4,544,637	10/01/1985	Keggins <i>et al.</i>			09/14/1982
	AH1	4,615,978	10/07/1986	Sandine <i>et al.</i>			12/18/1984
	AI1	4,620,908	11/04/1986	Van Duzer			06/18/1984
	AJ1	4,621,058	11/04/1986	Reddy			04/09/1984
	AK1	4,632,980	12/30/1986	Zee <i>et al.</i>			04/03/1985

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	GB 1 355 192	06/05/1974	Great Britain			Yes No
	AM1	CS 169,007	06/29/1976	Czechoslovakia			Yes X No
	AN1	WO 94/27645	06/29/1976	WIPO			Yes No
	AO1	JP 51-98354	08/30/1976	Japan			Yes X No
	AP1	EP 0 049 632 A2	04/14/1982	Europe			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Brock, T.D., <i>et al.</i> , "Acidity and pH," in <i>Biology of Microorganisms</i> , 4 <sup>th</sup> edition, Brock, T.D., <i>et al.</i> , eds., Prentice-Hall, Englewood Cliffs, NJ, p. 275 (1984)
	AS	1	Camire, J.C.F., <i>et al.</i> , "Efficient Cultivation of Cells Using Powdered Serum," <i>In Vitro</i> 34:Abstract No. V-1008 (March 1998)
	AT	1	Davis, B., <i>et al.</i> , in <i>Microbiology: Including Immunology and Molecular Genetics</i> , Ch. 67, 3rd Ed., Harper & Row, Philadelphia, pp. 1264-1274 (1980)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-149

MAR 17 2004

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

0942.4290008/RWE/FRC

APPLICATION NO.

10/685,802

FIRST NAMED INVENTOR

Fike *et al.*

FILING DATE

October 16, 2003

ART UNIT

1636

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	4,689,297	08/25/1987	Good <i>et al.</i>			03/05/1985
	AB2	4,820,627	04/11/1989	McGeeham			03/24/1986
	AC2	4,885,848	12/12/1989	Christensen			07/13/1988
	AD2	4,975,246	12/04/1990	Charm			01/23/1989
	AE2	4,999,301	03/12/1991	Bryan-Jones			09/27/1988
	AF2	5,006,204	04/09/1991	Jensen			10/31/1988
	AG2	5,133,137	07/28/1992	Petersen			02/05/1991
	AH2	5,155,039	10/13/1992	Chrisope <i>et al.</i>			07/22/1991
	AI2	5,325,606	07/05/1994	Liborius			12/23/1992
	AJ2	5,357,688	10/25/1994	Christensen			05/04/1993
	AK2	5,366,696	11/22/1994	Williams			01/07/1993

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	JP 57-152882	09/21/1982	Japan			Yes X No
	AM2	SU 1097253	06/15/1984	Soviet Union			Yes X No
	AN2	EP 0 155 427 A1	09/25/1985	Europe			Yes X No
	AO2	JP 1-157395	06/20/1989	Japan			Yes X No
	AP2	JP 2-57175	02/26/1990	Japan			Yes X No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Downes, <i>et al.</i> , "The relative value of irradiated spray-dried blood powder and heat-sterilized blood meal as measured in combination with whey protein," <i>Suid Afrikaanse Tydskrif Vir Veekunde (S. Afr. J. Anim. Sci.)</i> 17:55-58 (1987)
	AS	2	Frazier, W.C., and Westhoff, D.C., "General Principles of Food Preservation: Asepsis, Removal, Anaerobic Conditions," in <i>Food Microbiology</i> , 3 <sup>rd</sup> edition, Vastyan, J.E., and Bradley, J.W., eds., McGraw-Hill, Inc., New York, pp. 93-99, 122-123, 126-127, 143-153, 161, 434-436, 444-445 (1978)
	AT	2	Freshney, R.I., "The Culture Environment: II. Media and Supplements," In: <i>Culture of Animal Cells: A Manual of Basic Technique</i> , Alan R. Liss, Inc., New York, NY, pp. 74-78 (1983)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <b>INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO. 0942.4290008/RWE/FRC	APPLICATION NO. 10/685,802
	FIRST NAMED INVENTOR Fike <i>et al.</i>	
	FILING DATE October 16, 2003	ART UNIT 1636

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	5,392,531	02/28/1995	Christensen <i>et al.</i>			02/28/1994
	AB3	5,474,931	12/12/1995	DiSorbo <i>et al.</i>			09/21/1993
	AC3	5,518,709	05/21/1996	Sutton <i>et al.</i>			04/10/1992
	AD3	5,580,856	12/03/1996	Prestrelski <i>et al.</i>			07/15/1994
	AE3	5,700,426	12/23/1997	Schmitthausler <i>et al.</i>			11/30/1994
	AF3	5,756,046	05/26/1998	Winks <i>et al.</i>			06/15/1994
	AG3	5,773,279	06/30/1998	Miller <i>et al.</i>			11/27/1996
	AH3	5,811,406	09/22/1998	Szoka, Jr. <i>et al.</i>			06/09/1995
	AI3	5,869,321	02/09/1999	Franklin			08/20/1997
	AJ3	6,627,426	09/30/2003	Biddle <i>et al.</i>			05/23/2000
	AK3	6,383,810	05/07/2002	Fike <i>et al.</i>			03/13/1998

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	EP 0 356 071 A2	02/28/1990	Europe			Yes No
	AM3	JP 4-198137	07/17/1992	Japan			X Yes No
	AN3	DK 167090 B1	08/30/1993	Denmark			X Yes No
	AO3	WO 95/13867	05/26/1995	WIPO			Yes No
	AP3	WO 96/23868	08/08/1996	WIPO			Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>3</u>	GEA Process Technology Division, Aeromatic-Fielder Division, technical brochure entitled "Batch fluid beds: Customized fluid bed systems for solids processing," Columbia, MD
	AS	<u>3</u>	GEA Pharmaceutical Processing, Marketing brochure entitled "Plant and Process Technology by the GEA Companies," Columbia, MD
	AT	<u>3</u>	GIBCO BRL 1995-1996 Product Catalogue and Reference Guide, Life Technologies, Inc., Gaithersburg, MD (January 1995)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449  INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4290008/RWE/FRC	APPLICATION NO. 10/685,802
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	FILING DATE October 16, 2003	ART UNIT 1636

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4	2,835,586	05/20/1958	Peebles			07/27/1953
	AB4	6,140,121	10/31/2000	Ellington <i>et al.</i>			10/17/1996
	AC4	4,053,542	10/11/1977	Hup <i>et al.</i>			06/12/1975
	AD4	5,773,061	06/30/1998	Getler <i>et al.</i>			05/15/1996
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4	WO 97/11157	03/27/1997	WIPO			Yes No
	AM4	WO 97/38734	10/23/1997	WIPO			Yes No
	AN4	WO 97/42980	11/20/1997	WIPO			Yes No
	AO4	WO 98/15297	04/16/1998	WIPO			Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Hampel, C.A., and Hawley, C.G., <i>et al.</i> , "Sterilization (Industrial)," in <i>The Encyclopedia of Chemistry, 3<sup>rd</sup> edition</i> , Hampel, C.A., and Hawley, G.G., eds., Van Nostrand Reinhold Company, New York, pp. 1052-1053 (1973)
	AS	4	Hana, <i>et al.</i> , "Preservation of sera, protein fractions, and tissue cultures media by spray drying," (English language abstract for CS 169,007 (Document No. AM1)) <i>Chem. Abstracts</i> 88:17 Abstract No. 118717 (1978)
	AT	4	Harlow, E., and Lane, D., "Sampling Serum," in <i>Antibodies: A Laboratory Manual</i> , Cold Spring Harbor Laboratory (1988)

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	AA						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>5</u>	Hay, <i>et al.</i> , American Type Culture Collection Catalogue of Cell Lines and Hybridomas, 6th Ed., ATCC, Rockville, MD, p. 347 (1988)
	AS	<u>5</u>	Jensen, J.D., "(Some recent advances in) Agglomerating, Instantizing, and Spray Drying," <i>Food Technol.</i> 29:60-71, Institute of Food Technologists (1975)
	AT	<u>5</u>	Life Technologies, Inc., "GIBCO-BRL 1995-1996 Product Catalogue and Reference Guide," Thomson Print Services Ltd., Glasgow, Scotland, pp. 1-18, 1-24, and 1-7 (1995)

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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Life Technologies, Inc., "GIBCO-BRL 1996-1997 Catalogue for Cell Culture," Thomson Print Services Ltd., Glasgow, Scotland, p. 16 and p. 56 (1996)
	AS	<u>6</u>	Life Technologies, "GIBCO-BRL 1996-1997 Catalogue for Cell Culture," Thomson Print Services Ltd., Glasgow, Scotland, pp. 79-84 (1996)
	AT	<u>6</u>	Maa, Y-F., <i>et al.</i> , "Spray-coating of rhDNase on lactose: effect of system design, operational parameters and protein formulation," <i>Int. J. Pharm.</i> 144:47-59, Elsevier Science B.V. (November 1996)

EXAMINER	DATE CONSIDERED
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>1</u>	NIRO, Inc., Technical Bulletin No. 95001 entitled "Fluid Bed Multi-Processor," Aeromatic-Fielder Division, Columbia, MD (1995)
	AS	<u>1</u>	Reinert, J., and Yeoman, M.M., "Sterilisation," "Culture Media," and "Composition of Culture Media," in <i>Plant Cell and Tissue Culture: A Laboratory Manual</i> , Springer-Verlag, Berlin, Germany, pp. 74 and 76-77 (1982)
	AT	<u>1</u>	Robey, T.E., and Ryan, J.M., "A Comparison of the Effects of Powdered and Liquid Fetal Bovine Serum on Normal Human Cell Growth, Metabolism and Urokinase Formation," <i>In Vitro</i> 34:Abstract No. V-1007 (March 1998)

EXAMINER	DATE CONSIDERED
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	FIRST NAMED INVENTOR Fike <i>et al.</i>	
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>8</u>	Rohde, P.A., <i>et al.</i> , BBL Manual of Products and Laboratory Procedures, BBL-Becton Dickinson & Co., pp. 97, 101, 111, 123, 124 (1973)
	AS	<u>8</u>	Derwent World Patent Index, Accession No. 1976-78201X, English language abstract for JP 51-98354 (Document AO1)
	AT	<u>8</u>	Derwent World Patent Index, Accession No. 1982-91800E, English language abstract for JP 57-152882 (Document AL2)

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FORM PTO-1449  <b>INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO. 0942.4290008/RWE/FRC	APPLICATION NO. 10/685,802
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	AR	<u>9</u>	WIPDS Database on STN, Accession No. 85-005539, English language abstract for Soviet Union Patent Publication No. SU 1097253 (Document AM2)
	AS	<u>9</u>	Derwent World Patent Index, Accession No. 4411606, English language abstract for EP 0 155 427 A1 (Document AN2)
	AT	<u>9</u>	Derwent World Patent Index, Accession No. 1989-218070, English language abstract for JP 1-157395 (Document AO2)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>10</u>	Unverified English Translation of Japanese Patent Application Publication No. JP 2-57175 (Document AP2)
	AS	<u>10</u>	JPO English language abstract for JP 4-198137 (Document AM3)
	AT	<u>10</u>	Derwent World Patent Index, Accession No. 76-44200X/197624, English language abstract for DK 167090 (Document AN3)

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	AR	<u>11</u>	European Search Report for European Application No. EP 98 90 8542, completed September 9, 2002
	AS	<u>11</u>	"Granulated Media," in Microbiology Catalog, EM Science, Cincinnati, Ohio (1999)
	AT	<u>11</u>	Marketing brochure for EZMix Fermentation Media, Sigma, St. Louis, MO, publication date before October 1, 1996

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	AR	<u>12</u>	Product and Corporate Information, American Protein Corporation, < <a href="http://www.AmericanProtein.com/index.html">http://www.AmericanProtein.com/index.html</a> > (July 1999)
	AS	<u>12</u>	United States Patent Application No. 09/705,940, Fike <i>et al.</i> , filed November 6, 2000 (NOT PUBLISHED)
	AT	<u>12</u>	BBL Manual of Products and Laboratory Procedure, 5 <sup>th</sup> Edition, Cockeysville, MD, pg. 161-162 (1973)

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	AR	<u>13</u>	Fassolitis, A.C., <i>et al.</i> , "Serum substitute in epithelial cell culture media: Nonfat dry milk filtrate," <i>Applied and Environmental Microbiology</i> 42:200-203, American Society for Microbiology (1981)
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